Site Monitoring



Donna Harsh Mickie Speers

Agenda

- Goals
- Monitoring to Date & Schedule
- Scope of Monitoring & Our Experience
- Remote Source Verification
- PI Review & Action Items



Goals

The monitor's approach to a visit is to be enthusiastic, friendly, collaborative, provide education and good feedback to help your study team provide the best quality data and subject safety in the ESETT trial.



Site Monitoring Schedule

- Routine Interim Monitoring Visits
 - After second subject enrolled
 - At least one visit per year thereafter
- Close-Out Visit



Monitoring to Date

- 48 Visits at 35 sites
- 2 Remote visits
 - University of Kentucky
 - Nationwide Children's Hospital



Scope of Monitoring

- Regulatory
- Study Team Member Changes
- Facilities
- Informed Consent
- CRFs and source document verification



Our Experience thus Far

Areas of Concern

- Timing & Amount of Benzos
- Timing of EEGs
- AE Reporting
- Secondary Outcomes & Corresponding SAEs
- Prior Medications



Our Experience thus Far

What makes a great visit?

- Organized
- Access
- Data entered and reviewed with sources
- All visits scheduled
- Coordinator available
- EHR competency



CRF Submission Timeline

- Within 8 hours of enrollment
 - Enrollment, Randomization, Eligibility, Treatment Effect and Study Drug Infusion
- Within 24 hours of enrollment
 - Secondary Outcomes and Informed Consent Log
- Within 5 days of enrollment
 - Remaining CRFs except Hospital Discharge and End of Study which may occur after 5 days

Remote Source Verification

- 2 Visits completed
 - University of Kentucky
 - Nationwide Children's Hospital
- 17 Hospitals with approval
- 4 sites near approval



Remote Source Verification

- Helpful hints to get started
 - Obtain medical record access
 - Check with other study coordinators
 - Contact Medical Records, IT and/or Privacy Office



PI Review & Action Items

- End of Study Form & Clinical Summary Packet
- Monitoring Report Attestation
- Action Items



Questions?



Thank You!

